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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

LINDA METCALF and ROSS METCALF,)
) Case No.: 07-cv-03119-MLC-TBJ
Plaintiffs,)
) ANSWER AND ADDITIONAL
v.)) DEFENSES OF
) MERCK & CO., INC.
MERCK & CO., INC.,)
) JURY TRIAL DEMANDED
Defendant.)
)

Defendant, Merck & Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers the Complaint. Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

PARTIES - PLAINTIFFS

- 1. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 1.
- 2. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 2.
- 3. Merck denies each and every allegation of Paragraph 3, except Merck states that it is without knowledge as to whether and when Plaintiff ingested FOSAMAX®.

PARTIES - DEFENDANT

- 4. Merck admits the allegations of Paragraph 4.
- 5. Merck denies each and every allegation of Paragraph 5, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.
- 6. Merck denies each and every allegation of Paragraph 6, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.
- 7. Merck denies each and every allegation of Paragraph 7, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 7 inconsistent with that prescribing information.
- 8. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 8 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid, and denies any allegations in Paragraph 8 with respect to Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 8.

- 9. Merck denies each and every allegation of Paragraph 9.
- 10. Merck denies each and every allegation of Paragraph 10.
- 11. Merck denies each and every allegation of Paragraph 11.
- 12. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 12.
 - 13. Merck denies each and every allegation of Paragraph 13.
 - 14. Merck denies each and every allegation of Paragraph 14.
 - 15. Merck denies each and every allegation of Paragraph 15.
 - 16. Merck denies each and every allegation of Paragraph 16.
- 17. Merck denies each and every allegation of Paragraph 17, except that Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but respectfully refers the Court to said document for its actual language and full text.
 - 18. Merck denies each and every allegation of Paragraph 18.
 - 19. Merck denies each and every allegation of Paragraph 19.
 - 20. Merck denies each and every allegation of Paragraph 20.
- 21. Merck denies each and every allegation of Paragraph 21, except that Merck admits that Fosamax product sales in 2005 amounted to approximately \$3.19 billion.
- 22. Merck is without knowledge as to whether Plaintiff used FOSAMAX®.

 Merck denies the remaining allegations in Paragraph 22.
 - 23. Merck denies each and every allegation of Paragraph 23.
- 24. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX®. Merck denies the remaining allegations in Paragraph 24.

- 25. Merck denies each and every allegation of Paragraph 25.
- 26. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 26.
- 27. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 27.
 - 28. Merck denies each and every allegation of Paragraph 28.
 - 29. Merck denies each and every allegation of Paragraph 29.
- 30. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 30.
 - 31. Merck denies each and every allegation of Paragraph 31.
 - 32. Merck denies each and every allegation of Paragraph 32.
 - 33. Merck denies each and every allegation of Paragraph 33.

COUNT I: PLAINTIFFS V. MERCK PRODUCTS LIABILITY – FAILURE TO WARN (N.J.S.A. 2A:58C-2 et seq.)

- 34. Merck repleads its answers to Paragraphs 1 through and including 33, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
- 35. Merck denies each and every allegation of Paragraph 35, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information. To the extent that the allegations of Paragraph 35 are conclusions of law, no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck

respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

- 36. Merck denies each and every allegation of Paragraph 36.
- 37. Merck denies each and every allegation of Paragraph 37.
- 38. Merck denies each and every allegation of Paragraph 38.
- 39. Merck denies each and every allegation of Paragraph 39.
- 40. Merck denies each and every allegation of Paragraph 40.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs'
Complaint with prejudice and awarding Merck such other and further relief that the Court
may deem just and proper.

COUNT II PLAINTIFFS V. MERCK PRODUCTS LIABILITY – DEFECTIVE DESIGN (N.J.S.A. 2A:58C-2 et seq.)

- 41. Merck repleads its answers to Paragraphs 1 through and including 40, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
- 42. Merck denies each and every allegation of Paragraph 42, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information.
 - 43. Merck denies each and every allegation of Paragraph 43.
 - 44. Merck denies each and every allegation of Paragraph 44.
- 45. Merck denies each and every allegation of Paragraph 45, except that Merck states that it is without knowledge as to the manner in which Plaintiff utilized FOSAMAX® and respectfully refers the Court to the FDA-approved prescribing

information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information..

- 46. Merck denies each and every allegation of Paragraph 46.
- 47. Merck denies each and every allegation of Paragraph 47.
- 48. Merck denies each and every allegation of Paragraph 48.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs'

Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

COUNT III PLAINTIFFS V. MERCK PUNITIVE DAMAGES UNDER THE PRODUCTS LIABILITY ACT (N.J.S.A. 2A:58C-1)

- 49. Merck repleads its answers to Paragraphs 1 through and including 48, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
 - 50. Merck denies each and every allegation of Paragraph 50.
 - 51. Merck denies each and every allegation of Paragraph 51.
 - 52. Merck denies each and every allegation of Paragraph 52.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs'
Complaint with prejudice and awarding Merck such other and further relief that the Court
may deem just and proper.

COUNT IV PLAINTIFFS V. MERCK BREACH OF EXPRESS WARRANTY

- 53. Merck repleads its answers to Paragraphs 1 through and including 52 and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
- 54. Merck denies each and every allegation of Paragraph 54, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information.
- 55. Merck denies each and every allegation of Paragraph 55, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.
 - 56. Merck denies each and every allegation of Paragraph 56.
 - 57. Merck denies each and every allegation of Paragraph 57.
 - 58. Merck denies each and every allegation of Paragraph 58.
 - 59. Merck denies each and every allegation of Paragraph 59.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs'
Complaint with prejudice and awarding Merck such other and further relief that the Court
may deem just and proper.

COUNT V PLAINTIFFS V. MERCK VIOLATION OF THE CONSUMER FRAUD ACT

- 60. Merck repleads its answers to Paragraphs 1 through and including 59, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
- 61. The allegations of Paragraph 61 state a legal conclusion to which no response is required. To the extent that a response is required, Merck denies each and every allegation of Paragraph 61 and respectfully refers the Court to the relevant legal standard.
- 62. The allegations of Paragraph 62 state a legal conclusion to which no response is required. To the extent that a response is required, Merck denies each and every allegation of Paragraph 62 and respectfully refers the Court to the relevant legal standard.
- 63. The allegations of Paragraph 63 state a legal conclusion to which no response is required. To the extent that a response is required, Merck denies each and every allegation of Paragraph 63 and respectfully refers the Court to the relevant legal standard.
- 64. Merck denies each and every allegation of Paragraph 64, including each and every allegation of subparts (a) through (e).
 - 65. Merck denies each and every allegation of Paragraph 65.
 - 66. Merck denies each and every allegation of Paragraph 66.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs'

Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

COUNT VI PLAINTIFFS V. MERCK NEW JERSEY PRODUCTS LIABILITY ACT

- 67. Merck repleads its answers to Paragraphs 1 through and including 66, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
 - 68. Merck denies each and every allegation of Paragraph 68.
- 69. The allegations of Paragraph 69 state a legal conclusion to which no response is required. To the extent that a response is required, Merck denies each and every allegation of Paragraph 69 and respectfully refers the Court to the relevant legal standard.
 - 70. Merck denies each and every allegation of Paragraph 70.
 - 71. Merck denies each and every allegation of Paragraph 71.
 - 72. Merck denies each and every allegation of Paragraph 72.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs'
Complaint with prejudice and awarding Merck such other and further relief that the Court
may deem just and proper.

COUNT VII PLAINTIFFS V. MERCK LOSS OF CONSORTIUM

- 73. Merck repleads its answers to Paragraphs 1 through and including 72, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.
- 74. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 74.
 - 75. Merck denies each and every allegation of Paragraph 75.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs'

Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

ADDITIONAL DEFENSES

Discovery and investigation may reveal that any one or more of the following additional defenses should be available to Merck in this matter. Merck, therefore, asserts said additional defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these additional defenses as it may deem appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Merck demands strict proof of all claims and allegations contained in Plaintiff's Complaint that Merck has not expressly admitted. Further answering and by way of additional defense, Merck states as follows:

FIRST ADDITIONAL DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND ADDITIONAL DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD ADDITIONAL DEFENSE

This case is more appropriately brought in a different venue.

FOURTH ADDITIONAL DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH ADDITIONAL DEFENSE

Plaintiffs are barred from recovering against Merck because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by applicable federal law, including the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq.

SIXTH ADDITIONAL DEFENSE

To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn Plaintiffs directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to its prescribing physician. To the extent New Jersey law applies, Plaintiffs' claims are barred because Merck has discharged its duty to warn under N.J.S.A. 2A:58C-4 in its warning to prescribing physicians.

SEVENTH ADDITIONAL DEFENSE

Other persons or entities who are not parties to this suit were guilty of negligence which was the sole proximate cause of, or a contributing cause to, the damages alleged in the Complaint. Merck anticipates more specific information regarding the identity and potential liability of these non-parties will be developed during discovery. Accordingly, any damages awarded should be apportioned or reduced in accordance with the applicable law.

EIGHTH ADDITIONAL DEFENSE

The injuries and damages, if any, sustained by Plaintiffs resulted in whole or in part from their own contributory or comparative negligence and any damages recovered should be reduced and/or barred in accordance with the applicable law.

NINTH ADDITIONAL DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiffs knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH ADDITIONAL DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH ADDITIONAL DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiffs' misuse or abuse of FOSAMAX®.

TWELFTH ADDITIONAL DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiffs' pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH ADDITIONAL DEFENSE

Plaintiffs' claims for breach of warranty are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH ADDITIONAL DEFENSE

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH ADDITIONAL DEFENSE

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH ADDITIONAL DEFENSE

To the extent that Plaintiffs seek punitive damages, such claims are barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH ADDITIONAL DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiffs allege to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST ADDITIONAL DEFENSE

Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND ADDITIONAL DEFENSE

Plaintiffs' claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD ADDITIONAL DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred in whole or in part by failure to prevent or mitigate damages.

TWENTY-FIFTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH ADDITIONAL DEFENSE

With respect to each and every cause of action, Plaintiffs cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiffs' claims to a negligence cause of action.

TWENTY-SEVENTH ADDITIONAL DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiffs' claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH ADDITIONAL DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH ADDITIONAL DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the Constitution of the United States of America and the Constitution of the States of Ohio and New Jersey.

THIRTIETH ADDITIONAL DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST ADDITIONAL DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available

medical and scientific knowledge and further was manufactured and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND ADDITIONAL DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD ADDITIONAL DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH ADDITIONAL DEFENSE

Plaintiffs have not sustained an ascertainable loss of property or money.

THIRTY-FIFTH ADDITIONAL DEFENSE

Plaintiffs have not suffered any actual injury or damages.

THIRTY-SIXTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred under the doctrine of economic loss.

THIRTY-SEVENTH ADDITIONAL DEFENSE

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiffs for any amounts received from collateral sources.

THIRTY-EIGHTH ADDITIONAL DEFENSE

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling

for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

THIRTY-NINTH ADDITIONAL DEFENSE

Plaintiffs' claims of fraud are not pleaded with the required particularity.

FORTIETH ADDITIONAL DEFENSE

Plaintiffs' claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged under the law with regulating prescription drugs, including FOSAMAX®, and is specifically charged with determining the content of warnings and labeling for prescription drugs.

FORTY-FIRST ADDITIONAL DEFENSE

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to <u>Buckman Co. v.</u>

<u>Plaintiff's Legal Committee</u>, 531 U.S. 341 (2001).

FORTY-SECOND ADDITIONAL DEFENSE

There is no causal relationship between Merck or its activities described in the Complaint and any injuries or damages allegedly sustained by Plaintiffs.

FORTY-THIRD ADDITIONAL DEFENSE

To the extent Plaintiffs have settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

FORTY-FOURTH ADDITIONAL DEFENSE

To the extent Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any source for injuries in the Complaint, such benefits are not recoverable in this action under N.J.S.A. 2A:15-97.

FORTY-FIFTH ADDITIONAL DEFENSE

The defendant is not guilty of negligence and violated no duty owing to Plaintiffs.

FORTY-SIXTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs lack capacity and/or standing to bring such claims.

FORTY-SEVENTH ADDITIONAL DEFENSE

The extent of any risk associated with the use of Merck's product, the existence of which is not admitted, was, at the time of the distribution of the product by Merck, unknown and could not have been known by the use of ordinary care by Merck.

FORTY-EIGHTH ADDITIONAL DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrine of accord and satisfaction, res judicata, payment and/or release.

FORTY-NINTH ADDITIONAL DEFENSE

Plaintiffs' damages are barred or reduced by the doctrine of avoidable consequences.

FIFTIETH ADDITIONAL DEFENSE

With respect to Plaintiffs' demand for punitive damages, Merck specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of BMW of North

America v. Gore, 116 U.S. 1589 (1996), Cooper Industries, Inc. v. Leatherman Tool

Group, Inc., 532 U.S. 424 (2001), and State Farm Mut. Auto. Ins. Co. v. Campbell, 123

S.Ct. 1513 (U.S. 2003).

FIFTY-FIRST ADDITIONAL DEFENSE

To the extent that Plaintiffs attempt to seek equitable relief, Plaintiffs are not entitled to such relief because Plaintiffs have an adequate remedy at law.

FIFTY-SECOND ADDITIONAL DEFENSE

To the extent New Jersey law applies, Plaintiffs are barred from recovery and/or Plaintiffs' recovery is limited pursuant to the Comparative Negligence Act, N.J.S.A. 2A:15-5.1, et seq.

FIFTY-THIRD ADDITIONAL DEFENSE

Merck denies any liability on its part, but if Merck is ultimately found liable to Plaintiffs, then it shall only be liable for its equitable share of Plaintiffs' recovery since any liability which would be found against it will be insufficient to impose joint liability. In the alternative, the liability, if any, of Merck is limited by and pursuant to the New Jersey Joint Tortfeasor Contribution Act, N.J.S.A. 2A:53A-1, et seq.

FIFTY-FOURTH ADDITIONAL DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel or waiver.

FIFTY-FIFTH ADDITIONAL DEFENSE

Merck asserts all defenses available to it pursuant to N.J.S.A. 2A:58C-1, et seq., otherwise known as the New Jersey Product Liability Act.

FIFTY-SIXTH ADDITIONAL DEFENSE

Plaintiffs' claims are governed by Ohio law.

FIFTY-SEVENTH ADDITIONAL DEFENSE

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission manifested a flagrant disregard of the safety of persons who might be harmed by the product in question, as required by Ohio Revised Code Section 2307.80.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing the Complaint with prejudice and awarding Merck its reasonable costs and disbursements, including reasonable attorneys' fees as may be available by law, together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

Dated: July 11, 2007 HUGHES HUBBARD & REED LLP

A New York Limited Liability Partnership

Attorneys for Defendant

Merck & Co., Inc.

By: /s Bart A. Whitley

Wilfred P. Coronato (WC-6200) Bart A. Whitley (BW-3010)

CERTIFICATION

I hereby certify that the matter in controversy is not the subject of any other court, arbitration or administrative proceeding.

By: s/ Bart A. Whitley

Wilfred P. Coronato (WC-6200) Bart A. Whitley (BW-3010) **CERTIFICATION OF SERVICE**

I hereby certify that a copy of the within Answer was served this day by

electronic filing via CM/ECF notification and by overnight mail in compliance with Rule

5 of the Federal Rules of Civil Procedure upon counsel for plaintiff, David Jacoby, Tracy

A. Finken, Gregory S. Spizer, Anapol, Schwartz, Weiss, Cohan, Feldman & Smalley,

P.C., 1040 Kings Highway North, Cherry Hill, NJ 08034.

Dated: July 11, 2007

By: /s Bart A. Whitley

Wilfred P. Coronato (WC-6200)

Bart A. Whitley (BW-3010)

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